UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/480,472	06/06/95	MCDONOUGH	213/066

18M2/1001

RICHARD J WARBURG
LYON AND LYON
633 WEST FIFTH STREET
SUITE 4700
LOS ANGELES CA 90071

EXAMINER	
TRAN,P	
ART UNIT	**PAPER NUMBER**
1807	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

SUPPLEMENTAL **Office Action Summary**	Application No. 08/480,472	Applicant(s) McDONOUGH ET AL.
	Examiner Paul B. Tran	Group Art Unit 1807

☒ Responsive to communication(s) filed on *Jun 20, 1997* .

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *24-42, 48-51, and 54-101* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *24-42, 48-51, and 54-101* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

SUPPLEMENTAL DETAILED ACTION

1. The examiner acknowledges the receipt of Applicant's Election/Amendment, Paper No. 16. Claim 84 was amended and Claim 101 was added. Claims 24-42, 48-51 and 54-101 are pending before the examiner.

2. Applicant's election with traverse of Group II in Paper No. 16 is acknowledged. Upon further consideration, the election is being withdrawn. All claims are hereby examined on the merit.

3. The following rejections are supplemental to the rejections of Claims 24-42, 48-51 and 54-56, which are set forth in the Office action mailed July 10, 1996, Paper No. 8.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 57-61, 62-70, 74-77, 79-83, 84-87, 89-93 and 101 are rejected under 35 U.S.C. § 103 as being unpatentable over Rogall et al. or Normand et al.

Rogall et al. teaches a nucleic acid sequence which includes the sequence set forth in SEQ ID NO. 2 which is from the nucleotide sequence of *Mycobacterium tuberculosis* (Figure 3, nucleotides 147-177). Normand et al. teaches a nucleic sequence comprising the sequence set forth in SEQ ID NO. 7 (Figure 3, nucleotides 2712-2728).

It would have been *prima facie* obvious to an ordinary skill in the art at the time the instant invention was made to make a probe or a detectable nucleic acid hybrid for detecting *Mycobacterium tuberculosis*, or a composition comprising oligonucleotides for amplifying *Mycobacterium tuberculosis.* The artisan would have been motivated to do so because the nucleotide sequence for these probes, nucleic acid hybrids, and oligonucleotides used for detecting or amplifying *Mycobacterium tuberculosis* are taught in Rogall et al. With respect to the different regions of *Mycobacterium tuberculosis* targeted for a probe or a primer for detecting, it would have been obvious to select any regions thereon since Rogall et al. also teaches differentiation of detecting *Mycobacterium*, i.e., differentially detecting *Mycobacterium tuberculosis* from other *Mycobacterium* species.

5. Claims 71-73, 78 and 88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rogall et al. as applied to claims 67, 75 and 85 above, and further in view of Guatelli et al. in view of Schuster et al. (U.S. Patent No. 5,169,766).

Rogall et al. teaches a nucleic acid sequence which includes the sequence set forth in SEQ ID NO. 2 which is from the nucleotide sequence of *Mycobacterium tuberculosis* (Figure 3,

nucleotides 147-177). Guatelli et al. teaches a composition comprising a target RNA; T7 promoter-primer and primer both of which complementary to the target sequence near the 3' ends; RNAse H; T7 RNA polymerase; and reverse transcriptase (Figure 1). Not taught or suggested in Guatelli et al. are modified primers or promoter-primers. Schuster et al. discloses a method for amplifying nucleic acid using a promoter-primer blocked at the 3' end (Abstract; column 12, lines 18-36). Also disclosed therein is a kit comprising reagents including oligonucleotides and polymerases for practicing the method (column 12, lines 39-52).

It would have been *prima facie* obvious to an ordinary skill in the art at the time the instant invention was made to make an oligonucleotide or a composition comprising oligonucleotides which are modified as to be recognized by an RNA polymerase. The artisan would have been motivated to make an oligonucleotide or composition as claimed because it would enable the DNA synthesis method as taught in Guatelli et al. The artisan would also have been motivated to modify the promoter-primer because as disclosed in Schuster et al., the modification would prevent unwanted transcription which would affect the amplification procedure. Although in Schuster et al. the modified 3' end is blocked and in the instant invention, it is modified to reduce extension by polymerase as compared to an unmodified equivalent, absent unexpected results it would have been obvious to an ordinary skill in the art to reduce extension and combine modified and unmodified oligonucleotides to control the effect of arbitrary transcription from the unmodified oligonucleotides.

6. Claims 94-100 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rogall et al. in view of Hogan et al. (U.S. Patent No. 5,030,557).

Rogall et al. teaches a nucleic acid sequence which includes the sequence set forth in SEQ ID NO. 2 which is from the nucleotide sequence of *Mycobacterium tuberculosis* (Figure 3, nucleotides 147-177). Hogan et al. discloses a method of enhancing nucleic acid hybridization using a "helper" oligonucleotide together with a probe specific for the target nucleic acid (Abstract, Claim 23).

It would have been *prima facie* obvious to an ordinary skill in the art at the time of the instant invention to add at least one helper oligonucleotide to the composition or kit because Hogan et al. discloses that it would enhance the hybridization of nucleic acid.

7. Any inquiry concerning this communication or those earlier from the examiner should be directed to Paul B. Tran, Ph.D., whose telephone number is (703) 308-4040.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose phone number is (703) 308-0196.

Paper related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to the Chemical Matrix Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The facsimile numbers are (703) 305-3014 and (703) 305-4227. Information related to facsimile transmission should be directed to (703) 308-9378.

Paul B. Tran, Ph.D.
Art Unit 1807
9/29/97

W. GARY JONES
SUPERVISORY PATENT EXAMINER
GROUP 1800
9/29/97